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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/657,740	09/08/2003	John C. Salerno	01794/100H406-US1	8852
7278	7590	07/06/2005	EXAMINER	
DARBY & DARBY P.C. P. O. BOX 5257 NEW YORK, NY 10150-5257			DESAI, ANAND U	
			ART UNIT	PAPER NUMBER
			1653	

DATE MAILED: 07/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/657,740	<b>Applicant(s)</b> SALERNO ET AL.	
	<b>Examiner</b> Anand U. Desai, Ph.D.	<b>Art Unit</b> 1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 01 April 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 12-18, 20, 22-26, 28, 30-34, 36 and 40-49 is/are pending in the application.
- 4a) Of the above claim(s) 18, 20, 22-26, 28, 30-34, 36, 40, 41 and 45-47 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 12-17, 42-44, 48 and 49 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

*He*

### **DETAILED ACTION**

1. This office action is in response to Amendment filed on April 1, 2005. Claims 1-11, 19, 21, 27, 29, 35, and 37 have been cancelled. New claims 42-49 have been added.

2. Newly submitted claims 45-47 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the claims are drawn to originally restricted group III claiming an expression vector, and a method of enhancing expression of a protein in a host cell comprising coexpressing said protein with a small heat shock protein, and a thermo tolerant host cell genetically modified to express a small heat shock protein.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 45-47 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

3. Claims 12-17, 42-44, 48, and 49 are currently pending and are under examination.

#### **Withdrawal of Rejections**

4. The rejection of claims 12-17 under 35 U.S.C. 112, 2<sup>nd</sup> paragraph as being indefinite is withdrawn based on Applicants amendment.

5. The rejection of claims 12, 14, and 16 under 35 U.S.C. 102(b) as being anticipated by Kamei et al. (Biochemical and Biophysical Research Communications 231: 373-378 (1997)) is withdrawn based on Applicants amendment.

6. The rejection of claims 12, 14, and 16 under 35 U.S.C. 103(a) as being unpatentable over Andley et al. (Journal of Biological Chemistry 271(50): 31973-31980 (1996)) in view of Kamei

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et al. (Biochemical and Biophysical Research Communications 231: 373-378 (1997)) is withdrawn based on Applicants amendment.

## **Maintenance of Objections and Rejections**

### ***Claim Rejections - 35 USC § 112***

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 12, 14, 16, 42-44, 48, and 49 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claim is drawn to an isolated nucleic acid encoding a polypeptide described by functional characteristic. In particular, truncated  $\alpha$ -crystallin polypeptide that lack an N-terminal sequence and can form aggregates having a mass of approximately 60,000 Daltons (as in claim 12) and can prevent aggregation (as in claim 42). To satisfy the written description requirement, the specification must describe the invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. The specification does not clearly describe the structure, that is amino acids in the various truncated polypeptides that can be altered without affecting the function of a specific polypeptide. For one to be in possession of the claimed invention, the inventor would have to know the functional

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consequences of structural alterations. In particular, applicant is claiming truncated polypeptides that can form aggregates and that can prevent aggregates, therefore it is not clearly described as to which amino acids can be truncated as to effect the two distinct functions. Thus due to the limited predictability in the art, a skilled artisan would not find adequate support for the functional limitations of the polypeptides as disclosed in claims 12, and 42 in the specification. Claims 14, 16, 43, 44, 48, and 49 are rejected for depending on rejected claims 12 and 42, and not clearly describing the amino acids of the various truncated polypeptides that can be altered without affecting the function of a specific polypeptide.

***Claim Rejections - 35 USC § 102***

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 12-17, and 42-44 are rejected under 35 U.S.C. 102(b) as being anticipated by Caspers, G.J. et al. (Exp. Eye Res. 59(1): 125-126 (1994)). Caspers, G.J. et al. disclose an isolated nucleic acid sequence encoding a truncated human  $\alpha$ A-crystallin. Caspers, G.J. et al. also disclose the cloning of a cDNA sequence encompassing a region coding for amino acids 74-160 of  $\alpha$ A-crystallin. The isolated cDNA would hybridize with the stringency conditions disclosed, because there is 100% identity between the region encoding amino acids 74-160 of the disclosed truncated cDNA and the claimed truncated human  $\alpha$ A-crystallin. The encoded truncated  $\alpha$ -crystallin currently being claimed in dependent claim 13 is being interpreted to claim

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truncated polypeptides comprising more than just the first 51 N-terminal amino acids, such as a truncation up to amino acid 73, because the word “comprising” is interpreted to contain more than just the disclosed sequence (see Figure 1, and page 126, 1<sup>st</sup> indented paragraph on left hand column, current application, claims 12-17, and 42-44).

The nucleic acid sequence does anticipate claims 12-17, and 42-44. The isolated nucleic acid encodes a truncated protein that encompasses the disclosed polypeptide, therefore it inherently possesses the requisite functional characteristics. Feit et al. (2003, J. Pat. Trade. Off. Soc., Vol. 85, No. 1, pages 5-21) teach three criteria for inherency. (1) The most important criterion is certainty. Citing *In re Tomlinson* and *In re Zierden*, Feit et al. state that certainty is established when the reference process necessarily **results** in the claimed process as opposed to a **possibility**. (2) The second criterion is chronology; it will always happen. Feit et al. state that the chronological test is forward chronology. Citing *Eli Lilly and Co. v Barr Laboratories, Inc.*, Feit et al. argue that the claimed result must always be obtained based upon the prior art method. 3) The third criterion is the legal standard. Feit et al., citing *Continental Can*, state that the legal standard is whether the missing descriptive material would be so recognized by a person of ordinary skill in the art as necessarily present in the thing. It is recognized by a person of ordinary skill in the art that a disclosed protein structure will always produce a function based on structure, and since the isolated nucleic acid encodes a truncated protein that encompasses the disclosed polypeptide it inherently possesses the functional characteristics. Therefore the nucleic acid does anticipate claims 12-17, and 42-44.

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11. Claims 12-15, 42, and 43 are rejected under 35 U.S.C. 102(b) as being anticipated by Crack, J. (Masters Thesis, Dalhousie University Halifax, Nova Scotia June 2000). Crack, J. discloses an isolated nucleic acid sequence encoding a truncated  $\alpha$ -crystallin polypeptide. One of the nucleic acid sequences described has 180 nucleotides removed from the N-terminus (p26-N $\Delta$ 60). The cDNA clone encodes residues 61-192 of a truncated  $\alpha$ -crystallin polypeptide, and is therefore comprised of a truncated  $\alpha$ -crystallin polypeptide, wherein the N-terminal sequence comprises residues 1-51 of said wild-type protein that is currently claimed in dependent claim 13. Crack, J. discloses that the conserved  $\alpha$ -crystallin domain is located between amino acid residues 61-152, and it is reasonable to propose that the conserved sequences in the  $\alpha$ -crystallin domain are responsible for chaperone activity (see page 4, section 1.3. Domain structure of small heat shock/  $\alpha$ -crystallin proteins, 4<sup>th</sup>, 5<sup>th</sup>, and 7<sup>th</sup> sentences). Bacteria expressing the N-terminal truncated  $\alpha$ -crystallin polypeptide, p26-N $\Delta$ 60, exhibited higher tolerance to heat (see page 36, Figure 9, particularly p26-N $\Delta$ 60 clone and page 42, Section 4.3, 2<sup>nd</sup> paragraph; p26-N $\Delta$ 60 clone on page 11, Table 1, page 24, figure 4, and page 57-58, Appendix IV, current application, claims 12-15, 42, and 43).

### *Conclusion*

12. No claims are allowed.

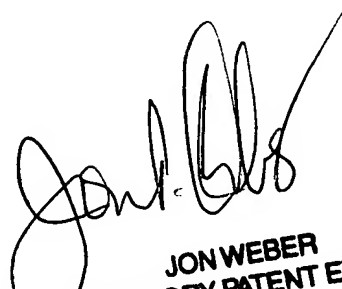
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anand U. Desai, Ph.D. whose telephone number is (571) 272-0947. The examiner can normally be reached on Monday - Friday 7:00 a.m. - 3:30 p.m..

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on (517) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

June 25, 2005

A handwritten signature in black ink, appearing to be a stylized 'A' or 'M' followed by a horizontal line.A handwritten signature in black ink, appearing to be 'Jon Weber' in a cursive style.

**JON WEBER**  
**SUPERVISORY PATENT EXAMINER**